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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,576	06/13/2001	Clifton A. Alfemess	11998.5USC2	7153
34379	7590	10/23/2003	EXAMINER	
ACORN CARDIOVASCULAR, INC. P.O. BOX 2903 MINNEAPOLIS, MN 55402			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	14
DATE MAILED: 10/23/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,576

Applicant(s)

ALFERNES ET AL. *CS*

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003 and 07 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 07 August 2003 is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

1. The amendment filed August 7, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New Figure 8 shows an implantable defibrillator, pacer leads and connection of the pacer leads to the heart.

Applicant is required to cancel the new matter in the reply to this Office Action. The amendment filed on August 7, 2003 contains new matter, and the amendment cannot be entered under 37 CFR 1.114 as an RCE. The above new matter can be only be added to the current specification through the filing of a continuation-in-part under 37 CFR 1.53(b).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the implantable defibrillator and the connection of the leads to the heart must be shown or the feature(s) canceled from the claim(s). **No new matter should be entered.**

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification states on Page 13, paragraph 3:

"The open areas of the knit construction also allows for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits the other procedures, e.g., coronary bypass, to be performed without removal of the jacket."

As clearly stated in the above paragraph from the specification, there is no reference to a defibrillator that is implanted for pacing the heart, although it merely states the "flexible construction permits passage of electrical elements (e.g., pacer leads) through the jacket". The above sentence does not constitute an enablement for the addition of a

Figure 8, which shows an implantable defibrillator and attachment to the heart.

Furthermore, there is no other reference in the specification disclosing a method using a defibrillator for pacing the heart in conjunction with the constraint device.

The specification only clearly designates a constraint device that is applied to the heart to treat cardiomyopathy. The specification does not disclose a method of using a defibrillator in conjunction with the constraint device to treat the heart, nor does it disclose the application of the defibrillator leads to the constraint device itself.

The Examiner requests the exact location of the above elements within the specification to withdraw the above rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness ('343) in view of Moore.

Alferness discloses a cardiac reinforcement device that comprises a biocompatible material that is configured to engage a surface of the heart to constrain circumferential expansion of the heart. See whole document.

Alferness however fails to disclose pacing the heart through the use of a cardiac pacing device and one or more pacing leads.

Moore discloses internal deployable defibrillator electrode and further discloses a pacing device and one or more pacing leads. See Column 1, lines 49-61; and Column 2, lines 56-68.

Since both Alferness ('343) and Moore disclose means for treating a disease of the heart it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the devices of Alferness ('343) and Moore to obtain a kit for treating a disease of the heart. It also would have been obvious to one of ordinary skill in the art to recognize that when the leads of Moore are placed on the heart, they can be placed on top of or beneath the jacket of Alferness ('343) to obtain leads that are operably connected to the constraint device while contacting the surface of the heart.

Response to Arguments

7. Applicant's arguments filed March 17, 2003 have been fully considered but they are not persuasive. In response to the argument that the specification enables the claims, the Examiner respectfully disagrees for the reasons set forth above. The mere statement that pacing leads can be placed through the knit construction does not constitute enablement for claiming the method steps for treating the heart using a constraint device and a defibrillator, a kit containing a constraint device and a defibrillator, and attaching leads to the knit of the constraint device to pace the heart. Furthermore, the drawings do not represent what is being claimed. The drawings are clearly representing the construction of the knit constraint device. There are no drawings or elements represented that can be interpreted as a defibrillator or the

attachment of leads to the knit construction to facilitate the pacing of the heart. "*The specification in combination with the knowledge of those of skill in the art at the time the invention*", as stated in the Remarks of March 17, 2003, does not constitute the enablement of the specification for Claims 18-31. (*emphasis added*)

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, The electrode system of Moore is disposed onto the surface of the heart to facilitate the pacing of the heart, rather than the traditional approach of surgically inserting the pacing leads through the vascular system into the chambers of the heart and then into the heart tissue to pace the heart. The jacket of Alferness is placed onto the surface of the heart to prevent or treat cardiomyopathy. Both Moore and Alferness utilize elements that are placed on the surface of the heart to treat the heart. Furthermore, Claims 20-22 pertain to a kit, with the elements of a cardiac constraint device and a cardiac pacing device. The combination of Moore and Alferness satisfies the limitations of the claims.

In response to applicant's argument that there is no motivation to combine the references of Moore and Alferness to attain a kit with the elements of a cardiac constraint device and a cardiac pacing device, a recitation of the intended use of the

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claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Continued Examination Under 37 CFR 1.114

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-2701. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

BS 


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